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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,294	11/17/2000	Narendra S. Yadav	CL1127 US CIP1	5868

23906 7590 10/26/2004

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WILMINGTON, DE 19805

EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/715,294	YADAV, NARENDRA S.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ashwin Mehta	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-43, 70 and 80-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-43, 70 and 80-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2003 and 03 February 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objections to claims 41, 82, 84, and 86 are withdrawn, in light of the claim amendments.
3. The rejection of claims 82, 84, 86, and 43 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, is withdrawn in light of the claim amendments.

### ***Claim Rejections - 35 USC § 112***

4. Claims 39-43, 70, and 80-86 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed February 17, 2004. Applicant traverses the rejection in the paper filed August 12, 2004. Applicant's arguments have been fully considered but were not found persuasive.

Applicant admits that the prior art did not teach the use of multiple SSR systems at the time the invention was made, but argue that the prior art did teach the use of single SSR species in plants. Applicant argues that the level of skill of one of ordinary skill in the art is high and

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that one of skill would have been able to make and use the invention using multiple SSR systems given the direction provided in the specification. Applicant argues that the presence of working examples is not determinative of whether working examples are required. In support of the notion that working examples are not required, Applicant cites two U.S. patents (response page 13, 1<sup>st</sup> full paragraph and the paragraph bridging pages 13-14). However, the cited U.S. patents issued after the filing date of the instant application. For an applicant to use a patent to prove the state of the art for the purpose of the enablement requirement, the patent must have an issue date earlier than the effective filing date of the application. See MPEP 2164.05(a). While working examples are not a requirement, Applicant has admitted that the level of predictability for the function of several independent SSR systems in one or more plants is low and one of skill in the art could not a priori predict with any reasonable certainty that combinations of these systems would indeed work, that one of skill in the art would not have had a reasonable expectation of success given the state of the art, as discussed in the previous Office action. Applicant has also stated that expression of certain recombinases are toxic to some tissues resulting in poor or no expression of the recombinases, and admit that it was unclear at the time the invention was made what effect the expression of several different SSR elements in multiple tissues would have on plant metabolism, also as discussed in the previous Office action. The specification does not provide guidance as to how one skilled in the art would overcome these deficiencies.

***Claim Rejections - 35 USC § 103***

5. Claims 39-41, 43, 70, 80, 81, 83, and 85 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Odell et al. "A" (Mol. Gen. Genet., 1990, Vol., 223, pages 369-378) in

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combination with Lloyd et al. (Mol. Gen. Genet., 1994, Vol. 242, pages 653-657), Applicant's admitted state of the prior art, and Odell et al. "B" (Use of Site-Specific Recombination Systems in Plants, in Homologous Recombination and Gene Silencing in Plants, 1994, pages 219-270, Ed. Paszkowski, J., Publisher: Kluwer, Dordrecht, Germany), for the reasons of record stated in the previous Office actions. Applicant traverses the rejection in the paper filed August 12, 2004. Applicant's arguments have been fully considered but were not found persuasive.

Applicant acknowledges the Examiner's observation of remarks stated in Odell et al. B regarding the specificity of various SSR systems, but fails to understand why that observation would suggest to the skilled person why multiple SSR systems would be functional in a single plant (response, page 16, 1<sup>st</sup> full paragraph). This comment, and the paragraph in which it is located, is an example of the state of the prior art, and indicates what was known about the specificity and efficiency of operation of SSR systems in the complex environment of plant cells. Given this specificity, one of ordinary skill in the art had a reasonable expectation of success in using two different SSR systems in plants without having one interfering in the operation of the other. Applicants also argue that the concept of activation of the second recombinase by the first recombinase was not suggested or anticipated by Odell et al. B, or other teachings (response, page 16, 1<sup>st</sup> full paragraph). However, it is not necessary that a reference actually suggest changes that Applicant made. See *In re Scheckler*, 438, F.2d 999, 1001; 168 USPQ 716, 717 (CCPA 1971). Modifications can be derived from an analysis of the prior art without a specific statement in the reference. See *In re Bozek* (416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969)), which teaches, "having established that this knowledge was in the art, the examiner could then properly rely...on a conclusion of obviousness 'from common knowledge and

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common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference’.”

Applicants also submit a declaration under 37 CFR 1.132, executed by Joan Odell, the principal author of Odell et al. B. Applicants argue that in the declaration, Dr. Odell declares that in her opinion, the present invention could not have been derived from the state of the art at the time the invention was made (response, page 2<sup>nd</sup> full paragraph). However, it is noted Dr. Odell is currently employed as a patent liaison in the patent group of the assignee of the instant application (declaration, page 2, 1<sup>st</sup> full paragraph), and as such is not a disinterested party. Dr. Odell also indicates, in reference to the teaching of Odell et al. B (page 260) discussed in the previous Office action, that at the time of publication it was thought that recombinases would function not at all or rarely on a plant chromosome, that the words, “quite impressive” in the publication refer to effectiveness relative to expectations of no or barely detectable recombination (declaration, page 3, 2<sup>nd</sup> full paragraph). However, no such discussion or comparison is mentioned in the reference. The reference promotes the advantages of the efficiency and specificity of SSR systems in plants.

### ***Summary***

6. Claims 39-43, 70, and 80-86 remain rejected.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### ***Contact Information***

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

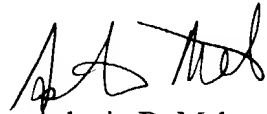
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

October 25, 2004

A handwritten signature in black ink, appearing to read 'Ashwin D. Mehta', written in a cursive style.

Ashwin D. Mehta, Ph.D.  
Primary Examiner  
Art Unit 1638